510(k) Summary: Sync-Rx System

This summary of substantial equivalence information is being submitted in accordance with the requirements set forth in 21 CFR 807.92.

K100849

Submitter: Sync-Rx Ltd.

Establishment Registration Number: Not Yet Assigned

Contact Information:

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MAY 21 2010

Date Prepared: January, 2010

Name of Device: Sync-Rx System

Classification Name: Angiographic X-ray System

Device Classification:

Classification: II
Classification Panel:
Regulation Number: 892.1600
Product Code: IZI

Predicate Device:

- Paieon IC Pro System v 3.2 system (K082907) manufactured by Paieon, Inc. (USA).
- QCA Plus (K915542) manufactured by Sanders Data Systems, (USA).

Device Description:

The Sync-Rx System is an image acquisition and processing workstation situated in the coronary catheterization lab and intended to be used during coronary catheterizations.

The Sync-Rx System captures the fluoroscopic image stream and performs the following functions for assisting the interventional cardiologist:

- Lesion Evaluation: The system performs angiogram selection and quantitative coronary measurements (lesion diameter, vessel diameter, lesion length, percent stenosis).
- Device positioning, deployment and post-deployment: An on-line enhanced image stream is displayed side-by-side to the existing fluoroscopic image stream.

All functions performed by the Sync-Rx System are presented, both in the procedure room and in the control room, on a display that is situated side by side to the already-existing display of the native fluoroscopic image stream.

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Indication for Use:

The Sync-Rx System, an image acquisition and processing modular software package, is indicated for use as follows:

- To provide quantitative information regarding the calculated dimensions of arterial segments.
- To enhance visualization of the stent deployment region.
- To be used in-procedure in the catheterization lab and off-line for post-procedural analysis.

Performance Standards:

This 510(k) submission was written in accordance with the FDA Guidance document "Guidance for the Submission of Premarket Notifications for Medical Image Management Devices- July 27, 2000", "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11 2005", and "General Principles for Software Validation; January 2002". The design of the Sync-Rx System conforms to the following voluntary standards:

- Digital Imaging and Communications in Medicine (DICOM): PS 3.3-2004, National Electrical Manufacturers Association.
- IEC/EN 60601-1-4:1997, General Requirements for Programmable Electrical Medical System.
- IEC 62304:2006, Medical Device Software – Software Lifecycle Processes.
- IEC/EN-60601-1: 1988 (2nd ed.), Medical Electrical Equipment; Part 1: General Requirements for Safety. Second edition, including amendments #1(1993), #2(1995) and #3(1996).
- IEC/EN 60601-1-2:2007, Medical Electrical Equipment; Part 1-2: Collateral Standard: Electromagnetic Compatibility- Requirements and Tests
- IEC 60601-1-6:2007, Medical electrical equipment – Part 1-6:General requirements for basic safety and essential performance – Collateral Standard: Usability
- EN 980:2008, Graphical Symbols For Use In The Labeling Of Medical Devices

Test Data:

The Sync-Rx System has been subjected to extensive safety, performance testing, and verification / validation. Final testing of the Sync-Rx System included various performance tests and software validation tests designed to ensure that the device meet all of its functional specifications and is fit for its intended use. Tests have also been performed to ensure the device complies with industry and safety standards. The following list summarizes the testing performed on the device;

- Software Verification and Validation Tests
- Sync-Rx System QCA Validation
- Sync-Rx System Usability Validation
- Input Device Mechanical Compliance
- Sync-Rx System Design Verification
- Electrical Safety
- Electromagnetic Compatibility

Substantial Equivalence:

The Sync-Rx System is substantially equivalent with respect to the indications for use, technological characteristics and performance characteristics to the identified legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Sync-Rx Ltd.
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MAY 21 2010

Re: K100849
Trade/Device Name: Sync-Rx System
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI
Dated: March 25, 2010
Received: March 26, 2010

Dear Mr. Anselmo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Sync-Rx System

Indications for Use:

The Sync-Rx System is an image acquisition and processing system. It is indicated for use as follows:

a) To provide quantitative information regarding the calculated dimensions of arterial segments.

b) To enhance visualization of the stent deployment region.

c) To be used in-procedure in the catheterization lab and off-line for post-procedural analysis.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100849